COVID-19 KEY EU DEVELOPMENTS POLICY & REGULATORY UPDATE

No. 24 | 13 October 2020

This regular alert covers key regulatory EU developments related to the COVID-19 situation. It does not purport to provide an exhaustive overview of developments and contains no analysis or opinion.

LATEST KEY DEVELOPMENTS

Competition & State Aid

- EU consults Member States on proposal to prolong and adjust State Aid Temporary Framework
- EU consults on public short-term export-credit insurance
- EU approves new and amended Member State measures to support the economy

Trade / Export Controls

- EU framework for screening foreign direct investment (FDI) becomes fully operational
- Commission expands Guidance on COVID-19-related humanitarian aid in sanctioned environments

Medicines, Medical Devices, and Personal Protective Equipment

- The European Medicines Agency starts first rolling review of a COVID-19 vaccine
- Commission signs third contract with a pharmaceutical company for access to a potential COVID-19 vaccine
- Drug developer Moderna will soon apply for rolling review of its vaccine in Europe
- Commission signs a Joint Procurement Framework Contract with Gilead for the supply of remdesivir

Cybersecurity, Privacy & Data Protection

- The Council of Europe publishes report on Digital Solutions to Fight COVID-19

COMPETITION & STATE AID

State Aid	
EU consults Member States on proposal to prolong and adjust State Aid Temporary Framework (see here)	On 2 October 2020, the European Commission launched a consultation with Member States on a draft proposal to prolong and adjust the State Aid Temporary Framework. In particular, the draft proposes to: – Prolong the validity of the Temporary Framework from its initial date of expiry (31 December 2020) to 30 June 2021; – Enable Member States to contribute to the fixed costs of companies that are not covered by their revenues. This additional form of support to companies seeks to avert the erosion of their capital, maintain their business activity and afford them with reinforced footing to recover; – Adapt the conditions for recapitalization measures under the Temporary Framework, in particular concerning the State's exit from enterprises where the State was an existing shareholder prior to recapitalization. Under the proposed changes, the State may exit from the equity of such enterprises through an independent valuation, while maintaining safeguards to uphold effective competition in the Internal Market. This would be the fourth amendment to the Temporary Framework, which has opened the way over the past seven months to nearly €3 trillion in Member State potential support to businesses most impacted by the coronavirus pandemic.
EU consults on public short-term export-credit insurance (see here)	The European Commission holds that export subsidies can adversely affect competition and has long condemned export aid for intra-EU trade and for exports outside the EU (*see Jones Day Update No. 2 of 3 April 2020*). Thus, the Commission has regulated State aid in the area of short-term export-credit insurance, not only among exporters in different Member States, but also among export-credit insurers operating in the EU. Under the 2012 Short-term export-credit Communication, for trade within the EU and certain non-EU countries listed in its Annex (with a maximum risk period of up to two years), this entails “marketable risks” and, in principle, should not be insured by the State or State supported insurers. As private insurers may ordinarily offer such insurance, the Commission considers that the State is not needed to offer similar insurance. However, in light of the coronavirus crisis and the resulting insufficiency of private insurance capacity for exports to all countries, the Commission decided on 27 March 2020 to temporarily remove all countries from the list of “marketable risk" countries under the Short-term export-credit Communication until 31 December 2020. This enabled Member States to make available public short-term export credit insurance. The Commission is now studying whether the current market situation may justify maintaining the derogation. Towards establishing whether sufficient private capacity currently exists to ensure exports to these “marketable risk” countries, the Commission opened a public consultation on 30 September 2020, allowing Member States, credit insurers and other interested parties to provide comments until 7 October 2020.

EU approves new and amended Member State measures to support the economy (see here)	Since the onset of the coronavirus outbreak, the European Commission has adopted a significant number of State aid measures under Article 107(2)b, Article 107(3)b and under the Temporary Framework. The most recent measures adopted to support the economy and companies affected by coronavirus outbreak include: • €57 million prolongation of Swedish scheme to compensate damages caused by cancelled or postponed cultural events due to the coronavirus outbreak • €403 million scheme to reimburse costs borne by Italian companies for reducing contagion risks in the workplace • €19.3 million Romanian loan guarantee to compensate TAROM for damage suffered due to the coronavirus outbreak • €61 million Lithuanian scheme to support research, development and production of coronavirus-relevant products • €1.5 billion Italian scheme to support companies affected by the coronavirus outbreak in Southern Italy • €15.8 million Belgian scheme to support hotels and aparthotels in Brussels in context of the coronavirus outbreak

TRADE / EXPORT CONTROLS

EU framework for screening foreign direct investment (FDI) becomes fully operational (see here)	On 11 October 2020, the framework established under the FDI Screening Regulation, adopted in March 2019, became fully operational. To recall, the EU Commission issued Guidance in March 2020, addressing foreign direct investment in the context of the current COVID-19 crisis (*see Jones Day Update No. 1 of 27 March 2020*). The Guidance highlighted that critical EU industries, particularly in the healthcare sector, face an increased risk of foreign takeovers during this pandemic. It thus called upon all Member States to set up a fully-fledged screening mechanism to ensure a strong EU-wide approach to foreign investment screening. Under the FDI Screening Regulation, Member States are empowered to screen foreign direct investments on grounds of security or public order, including health security. For EU Member States currently without an FDI screening mechanism, the Regulation does not mandate adopting such a mechanism. However, it establishes certain core requirements for new or existing Member State mechanisms. In addition, the Regulation: • creates a cooperation mechanism to enable Member States and the Commission to exchange information and to raise concerns related to specific investments; • enables the Commission to issue opinions when an investment poses a threat to security or public order in more than one Member State, or when an investment could undermine a project or programme of EU interest. The Commission indicates that several Member States are currently in the course of adopting new screening mechanisms, or reforming existing mechanisms, to comply with the Regulation.

Commission expands Guidance on COVID-19-related humanitarian aid in sanctioned environments (see here)	The European Commission has expanded its Guidance Note on how COVID-19-related humanitarian aid can be provided to countries around the world that are subject to EU sanctions (*see Jones Day Update No. 8 of 15 May 2020*). Specifically, the Guidance now contains dedicated chapters on Iran and Venezuela, building on the first chapter of the Guidance Note concerning Syria, published in May 2020. To recall, the Guidance Note informs competent authorities of EU Member States, as well as public and private operators involved in humanitarian activities, on how to comply with EU sanctions when providing humanitarian aid to fight the coronavirus pandemic.

MEDICINES, MEDICAL DEVICES, AND PERSONAL PROTECTIVE EQUIPMENT

The European Medicines Agency starts first rolling review of a COVID-19 vaccine (see here)	On 1 October 2020, the European Medicines Agency (EMA) started the rolling review of the AstraZeneca COVID-19 vaccine, based on promising preliminary results from non-clinical and early clinical studies. Under the rolling review process, the EMA reviews data on medicinal products as they become available from ongoing studies and prior to the submission of a marketing authorization (MA) application, in view of speeding up regulatory approval. The rolling review was previously used in the assessment of Veklury (remdesivir), the first medicinal product to be granted an MA in the EU for the treatment of COVID-19 (*see Jones Day Update No. 15 of 3 July 2020*).
Commission signs third contract with a pharmaceutical company for access to a potential COVID-19 vaccine (see here)	On 8 October 2020, the European Commission signed an agreement with Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, for the purchase of 200 million doses of a potential vaccine, once it is proven to be safe and effective against COVID-19. Under the contract, Member States may also decide to purchase an additional 200 million doses of the vaccine, donate the vaccine to non-EU lower and middle income countries or re-direct it to other European countries. This is the third agreement that the Commission has concluded with a pharmaceutical company, following its earlier contracts with AstraZeneca and with Sanofi-GSK.
Drug developer Moderna will soon apply for rolling review of its vaccine in Europe (see here)	On 8 October 2020, Moderna Inc announced that it will soon apply to the European Medicines Agency (EMA) for real-time reviews of its experimental COVID-19 vaccine. This follows the recent launch of such reviews by the EMA of vaccines developed by AstraZeneca (see above) as well as those of US drugmaker Pfizer and Germany's BioNTech.
Commission signs a Joint Procurement Framework Contract with Gilead for the supply of remdesivir (see here)	On 8 October 2020, the European Commission signed a Joint Procurement Framework Contract (JFC) with Gilead for the supply of up to 500,000 treatment doses of Veklury (the brand name for remdesivir), with the option to purchase additional doses. Member States can now place their orders under the JFC. Veklury is currently the only medicine that has been granted conditional marketing authorisation in the EU for the treatment of COVID-19 patients needing oxygen supply.

CYBERSECURITY, PRIVACY & DATA PROTECTION

The Council of Europe publishes report on Digital Solutions to Fight COVID-19 (see here)	On 12 October 2020, the Council of Europe published a report on Digital Solutions to Fight COVID-19 ("Report"). The Report analyzes the impact on rights to privacy and data protection of measures to contain the COVID-19 pandemic in the countries Parties to Convention 108 (i.e., a binding international instrument protecting individuals against abuses arising from the collection and processing of personal data). The Report provides a technical review of the use of digital contact tracing applications and monitoring tools. In particular, a number of shortcomings have been identified regarding the legal and technical measures adopted to fight the COVID-19 virus (e.g., unlawful processing of personal data). Hence, the Report stresses the need for enhanced transparency of digital solutions in order to ensure greater respect of the rights to privacy and data protection. Additionally, the Report highlights a lack of cooperation and interoperability of digital solutions amongst the countries Parties to Convention 108.

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